K070997

510(k) Notification

DORO® Non-Stick Bipolar Forceps, DORO® Bipolar Reusable Cables and Accessories

APPENDIX I: Summary

1. Device Name

Trade Name: DORO® Non-Stick Bipolar Forceps
DORO® Bipolar Reusable Cables

Common Name: Bipolar Forceps
Bipolar Reusable Cables

MAY 16 2007

2. Classification

The DORO® Non-Stick Bipolar Forceps and DORO® Bipolar Reusable Cables of pro med instruments GmbH can be classified according following Device Names and Product Codes:

Device **Device description**	Device, Electrosurgical, Cutting & Coagulation & Accessories Electrosurgical cutting and coagulation device and accessories.
Medical Specialty	Part 878, General & Plastic Surgery
Product Code	GEI
Regulation Number	878.4400
Device Class	2
Description acc. 21 CFR 878.4400: PART 878--GENERAL AND PLASTIC SURGERY DEVICES Subpart E--Surgical Devices Sec. 878.4400 Electrosurgical cutting and coagulation device and accessories. (c) Identification. An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current. (d) Classification: Class II.	

3. Substantial Equivalence

(a) DORO® Non-Stick Bipolar Forceps:

The **DORO® Non-Stick Bipolar Forceps** are substantially equivalent to other legally marketed Bipolar Forceps from different manufacturers, Günter Bissinger Medizintechnik GmbH (product: CLARIS NON-STICK bipolar forceps, K51429), e.g. Link Technology, Inc. (product: Silverglide Surgical Technologies, K992931).

The DORO® Non-Stick Bipolar Forceps are for use in general surgical procedures. These devices are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. The forceps are designed to grasp and manipulate selected tissues. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch.

During the coagulation of tissue, the coagulated tissue may stick to the tip of the forceps. This undesirable effect can be eliminated by the non-stick properties of the unique solid silver alloy tip forceps of the DORO line. The solid silver alloy tip provides excellent thermal properties and eliminates the difficult and time-consuming cleaning of the forceps during a procedure. The non-stick properties are permanent since it is not a coating and the non-stick properties are retained through repeated and frequent sterilizations.

Reusable Standard two-pin round connector cables are designed to work well with all foot-switching bipolar electrosurgical generators.

(b) DORO® Bipolar Reusable Cables

The DORO® Bipolar Reusable Cables are equivalent to the Stryker Silverglide Bipolar Forceps Reusable Cables (K061835) and nearly equivalent to CLARIS bipolar forceps (K051429) except small changes of the material.

The DORO® Bipolar Reusable Cables are non-sterile, reusable bipolar cables of 3 and 5 meters. They are designed to transport electrical power from a high-frequency electrosurgical generator by a foot-activated switch. The cable fittings are compatible for use with: Erbe, Martin, Valleylab, Aesculap and other ES Generator Units with twin-pin connectors (2-banana plug). The cables are comprised of silicone (outer insulation), PTFE or FEP (core insulation), and Cu-wire poreless silver plated (wire).

The cable consists of a twin-pin connector (2-banana plug) that is comprised of silver plated bronze and insulated with silicone. The connector cable at the forceps end is comprised of bronze or brass - silver or nickel plated, Stainless Steel 1.4310, PP (Polypropylene or TPE).

5. Intended Use

(a) DORO® Non-Stick Bipolar Forceps

The DORO® Non-Stick Bipolar Forceps are designed to grasp, manipulate and coagulate selected tissue and are intended for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch.

The DORO® NON-STICK Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

(b) DORO® Bipolar Reusable Cables

The DORO® Bipolar Reusable Cables are designed to conduct electrical power from the output of a high frequency electrosurgical generator to the instrument.

6. Performance Standards

DIN EN 60601-1: Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988 + A1:1991 + A2:1995); German version EN 60601-1:1990 + A1:1993 + A2:1995; Version: 01-Mar-1996;

DIN EN 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:1998); German version EN 60601-2-2:2000; Version: 01-Aug-2001;

ANSI/AAMI HF18-2001: Electrosurgical Devices; Version: 01-May-2001.

7. Sterilization by User

DORO® Non-Stick Bipolar Forceps and DORO® Bipolar Reusable Cables are delivered in non-sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.

Cleaning and Maintenance

Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc.

Do not use damaged instruments.

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

Instruments must be completely cleaned and rinsed of all foreign matter.

Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners (such as Enzol™) must be used to remove protein deposits. Follow the enzymatic cleaner's instructions; rinse thoroughly.

Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.

Do not use abrasive cleaners.

Only a soft bristle brush should be used.

Immerse the entire device in detergent and clean while soaking.
Rinse with sterile deionized water.
Can be disinfected in the washing machine up to 203°F (95°C).

Rinse thoroughly with distilled water.

Prepare for storage and/or sterilization.

Sterilization

Only a validated steam-sterilization process according DIN EN 554 / ISO 11134 that uses a sterilization cycle of 137°C / 280°F, 3 bar, for min. 15 minutes should be used.

(Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)

Caution: Autoclave temperatures should not exceed 280°F (137°C); handles, insulation or other non-metallic parts may be damaged

Do not sterilize with hot air.

Do not use 'Flash' autoclave procedures.

8. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that DORO® Non-Stick Bipolar Forceps are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pro Med Instruments GmbH
% Pro Med Instruments, Inc.
Mr. Edgar Schuele
Managing Director
5450 Lee Street, Suite 1
Lehigh Acres, Florida 33971

MAY 16 2007

Re: K070997
Trade/Device Name: DORO® Non-Stick Bipolar Forceps
DORO® Bipolar Reusable Cables
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 5, 2007
Received: April 13, 2007

Dear Mr. Schuele:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification K070997

DORO® Non-Stick Bipolar Forceps, DORO® Bipolar Reusable Cables and Accessories

APPENDIX II: Indication Of Use Statement

Company:	pro med instruments GmbH
510 (K) Number (if known):	K070997
Device Name:	**DORO® Bipolar Reusable Cables**
Classification Name:	Electrosurgical Cutting and Coagulation Device & Accessories
Product Code:	GEI, Class II 21 CFR 878.4400

INDICATION OF USE

The DORO® Bipolar Reusable Cables are designed to conduct electrical power from the output of a high frequency electro-surgical generator to the instrument.

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

(Division Sign-off)

Division of General, Restorative, and Neurological Devices

510(K)Number K070997

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PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE AN ANOHTER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801 Subpart D) or Over-The Counter Use ____ (Per 21 CFR 801 Subpart C)

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(Division Sign-off)

Division of General, Restorative, and Neurological Devices

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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